UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

Biosig Instruments, Inc.

JURY TRIAL DEMANDED

Plaintiff,

v. Case No. 10-cv-7722 (AKH)

Nautilus, Inc.

Defendant.

BIOSIG INSTRUMENTS, INC.'S OPPOSITION TO NAUTILUS, INC.'S MOTION FOR SUMMARY JUDGMENT OF INVALIDITY AND NONINFRINGEMENT

(PORTIONS OF THIS DOCUMENT HAVE BEEN REDACTED PURSUANT TO THE STIPULATED PROTECTIVE ORDER ENTERED BY THE COURT ON MARCH 8, 2011)

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I. INTRODUCTION

Nautilus incorrectly asserts that it is entitled to summary judgment of noninfringement on an issue that it never moved on in the prior litigation between the parties. If Nautilus' products do not infringe for the reasons Nautilus now states, then Nautilus would have brought this motion years ago instead of instituting two reexamination proceedings in the Patent Office. But now after having been unsuccessful in its attempts to have the Patent Office invalidate the claims, Nautilus asserts a new noninfringement defense. In any event, this new defense lacks merit as Nautilus has not even explained why its products do not have the claim limitations, and there is substantial evidence even with limited discovery that Nautilus' products have the allegedly missing claim limitations. Further, as there has been no discovery in the current action and limited discovery was conducted in the previous action, Nautilus motion should be rejected and a discovery schedule should be ordered.

Nautilus also alleges incorrectly that Biosig's patent claims are invalid. But Nautilus' arguments are without merit, as they are just a rehashing of its arguments that were already considered and rejected by the Patent Office. Further, Nautilus relies on mere attorney assertion which is insufficient for Nautilus to satisfy its heavy burden of establishing invalidity by clear and convincing evidence as a matter of law, particularly in light of Biosig's experts' validity opinions.

II. SUMMARY JUDGMENT OF NONINFRINGEMENT IS INAPPROPRIATE

Nautilus' motion for summary judgment of noninfringement should be rejected for three reasons. First, the parties have only conducted a very limited amount of discovery, so summary judgment is premature. Second, Nautilus has failed to satisfy its summary judgment burden of coming forward with evidence of how the Nautilus products operate and pointing out the claim limitations that are supposedly absent from Nautilus' products. Third, Biosig has submitted

evidence sufficient to create a genuine issue of material fact on the infringement issues. Rather than granting Nautilus' premature summary judgment motion, Biosig requests that this Court enter a case schedule for the orderly completion of discovery. Biosig has submitted a proposed case schedule as Exhibit E to the concurrently filed Bonella Declaration.

A. Factual Background: Little Discovery Was Conducted in the Prior Case and No Discovery was Conducted in the Refiled Case

After unsuccessfully attempting to license the '753 Patent to Nautilus, Biosig filed a patent infringement action against Nautilus in this Court (*Biosig Instruments, Inc. v. The Nautilus Group, Inc.*, 04-cv-06654-AKH (S.D.N.Y.) ("The First Nautilus Litigation"). During that proceeding, Nautilus instituted a reexamination of Biosig's patent by the U.S. Patent & Trademark Office ("Patent Office"). Based on the reexamination, the parties agreed to a stay, and the Court dismissed the case without prejudice and subject to a tolling agreement in March 2009. After the dismissal, Nautilus instituted a second reexamination proceeding. In June 2010, the Patent Office issued a notice of its intent to confirm the patentability of Biosig's '753 patent claims without amendment, and issued the reexamination certificates on October 20, 2010.

In the First Nautilus Litigation, little discovery was conducted. Nautilus produced only about 30,000 pages of documents, most of which was alleged prior art and publicly available information. (Bonella Dec. at ¶3). No fact depositions were taken. (*Id.*). No discovery of Nautilus' third-party vendors who manufacture the monitors on Nautilus' behalf was conducted, as Nautilus instituted the reexaminations and the case was dismissed before fact discovery really got off the ground. (*Id.* at ¶2).

No discovery has been conducted in the refiled case. Biosig refiled its complaint on October 8, 2010, and Nautilus answered on January 3, 2011. The Court initially ordered the parties to prepare a proposed Case Management Plan. (*Id.* at ¶5). Both parties recognized that a

substantial amount of discovery was needed and agreed to a proposed discovery plan (*Id.*, at Ex. C). In Biosig's and Nautilus' proposed discovery schedule, non-expert discovery was proposed to extend about a year from about March 2011 until February 28, 2012, and a schedule for dispositive motions and completion of expert discovery was to be determined after February 28, 2012, but no later than March 29, 2012. (*Id.* at Ex C, 1-2). At the soonest possible time, Biosig sought fact discovery, as it served document requests and interrogatories on Nautilus immediately after the Fed. R. Civ. P. 26(f) conference in March 2011 (*Id.* at Exs. A-B). Likewise, Nautilus served discovery on Biosig. (*Id.* at Exs. F-H).

At the Case Management Conference in March 2011, however, the Court decided to put off discovery and proceed directly to the Claims Construction Hearing. As such, the parties exchanged claims constructions, worked to narrow the issues, and conducted claims construction briefing between March 2011 and August 2011, with the Court issuing its Claims Construction Order on September 29, 2011 (D.I. 32). During this time, no discovery occurred. (Bonella Dec. at ¶7). Specifically, there have not been any depositions of Nautilus personnel or any vendors that supply heart rate monitoring equipment to Nautilus in either the First Nautilus Litigation or the current litigation; there has not yet been discovery of the heart rate monitor vendors' documents; and the documents produced by Nautilus do not include information on all of the relevant products. (*Id.* at ¶¶3, 10). With the absence of this fact discovery, expert discovery was necessarily prevented and has not yet occurred.

B. Nautilus' Motion for Summary Judgment Should be Denied Under Fed. R. Civ. P. 56(d) Because the Parties Have Not Conducted Discovery

Nautilus' products lack the claimed "means for measuring" and "means for calculating." According to Nautilus, Biosig cannot rely on FED. R. CIV. P. 56(d), which permits a party to

oppose a motion for summary judgment on the grounds that discovery is needed. But Nautilus is wrong because Biosig is entitled to due process and to conduct fact discovery. Both the claimed "means for measuring" and the "means for calculating" relate to the confidential internal signal processing in Nautilus' devices. Nautilus and its vendor-manufacturers consider this information confidential as what limited information that has been produced has been designated confidential under the protective order. *E.g.*, Yanulis Dec. at Exs. C-G.¹ The best evidence of Nautilus' confidential signal processing is in the hands of Nautilus, its former employees, and Nautilus' vendors. However, there was limited discovery in the prior action and no discovery in this action. Accordingly, it violates all notion of fairness to grant summary judgment without affording Biosig discovery on Nautilus' confidential information.

In fact, Fed. R. Civ. P. 56(d) specifically prevents Nautilus from obtaining summary judgment prior to discovery being conducted as it provides: "[i]f a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may: (1) defer considering the motion or deny it; (2) allow time to obtain affidavits or declarations or to take discovery; or (3) issue any other appropriate order." Fed. R. Civ. P. 56(d); *Plunkett v. City of New York*, 2011 U.S. Dist. LEXIS 100471 (S.D.N.Y. Sept. 2, 2011) (holding a motion for summary judgment premature because no discovery had been taken yet). The purpose of Fed. R. Civ. P 56(d), as interpreted by the Second Circuit, is to provide a party, after a reasonable request, a means for obtaining discovery in order to defend against a motion because "summary judgment should only be granted if 'after discovery, the nonmoving party has failed to make a sufficient showing on an essential element of [its] case with respect to which [it] has the burden of proof." *Miller v. Wolpoff & Abramson, L.L.P.*, 321 F.3d 292, 303 (2d Cir. 2003)

¹ "Yanulis Dec." refers to the concurrently filed Declaration of Dr. George Yanulis, Biosig's Infringement and Validity expert.

(emphasis in original) (quoting *Hellstrom v. United States Dep't of Veterans Affairs*, 201 F.3d 94, 97 (2d Cir. 2000)). Indeed, "[o]nly in the rarest of cases may summary judgment be granted against a plaintiff who has not been afforded the opportunity to conduct discovery." *Hellstrom*, 201 F.3d at 97.²

Biosig has satisfied FED. R. CIV. P. 56(d) because it has submitted declarations from counsel and its technical expert, Dr. Yanulis, setting forth the fact discovery that is required in this action.³ (Bonella Dec. at ¶11; Yanulis Dec. at 2). The facts sought by Biosig are reasonably expected to create a genuine issue of material fact because they are reasonably expected to describe the precise way in which the accused Nautilus devices operate, which Biosig believes will confirm Nautilus' infringement. ⁴ For example, on March 7, 2011, Biosig served Requests for Documents and Things and Interrogatories on Nautilus, however, this discovery remains unanswered. (*Id.* at ¶4, Exs. A-B). Biosig also intended to serve subpoenas on third parties, such as Polar USA, Polar Electro, Inc, and Salutron Inc., who were identified in the First Nautilus Litigation as supplying equipment to Nautilus, but did not when the Court ordered that no discovery should be conducted at the initial case management conference. (*Id.* at ¶6-7). From

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² Trebor Sportswear Co. v. The Ltd. Stores, Inc., 865 F.2d 506, 511 (2d Cir. 1989) ("The nonmoving party must have had the opportunity to discover information that is essential to his opposition to the motion for summary judgment." Commercial Cleaning Servs., L.L.C. v. Colin Serv. Sys., Inc., 271 F.3d 374, 386 (2d Cir. 2001) ("explaining that the court should defer decision of a motion until the party has had the opportunity to take discovery and rebut the motion")

³ "[A] party resisting summary judgment on the ground that it needs discovery in order to defeat the motion must submit an affidavit showing '(1) what facts are sought [to resist the motion] and how they are to be obtained, (2) how those facts are reasonably expected to create a genuine issue of material fact, (3) what effort affiant has made to obtain them, and (4) why the affiant was unsuccessful in those efforts." *Gurary v. Winehouse*, 190 F.3d 37, 43 (2d Cir. 1999) (quoting *Meloff v. N.Y. Life Ins. Co.*, 51 F.3d 372, 375 (2d Cir. 1995)).

⁴ *Miller*, 321 F.3d at 303 ("While the affidavit did not specify with precision the information plaintiff believed he could learn from deposing the three affiants, plaintiff cannot be faulted for failing to advise the district court precisely what information he might learn during discovery given that the facts sought were exclusively within defendants' possession")

publicly available information and independent research, Biosig already formed a strong foundation in support of Nautilus' infringement of the '753 Patent, however, in complex electronics and software cases, discovery is needed to fully understand the operation of the accused devices. *O2 Micro Int'l, Ltd. v. Monolithic Power Sys.*, 467 F.3d 1355, 1365 (Fed. Cir. 2006) (discussing how limiting discovery necessarily "conflict[s] with the spirit, if not the letter, of the broad discovery regime under the Federal Rules of Civil Procedure, especially given the particular importance of discovery in complex patent cases"). Therefore, in order to obtain discovery, Biosig proposes a discovery schedule similar to the schedule originally agreed to by the parties in the originally proposed Case Management Plan. (Bonella Dec., at ¶13, Exs. C, E).

Nautilus' only answer to Biosig's need for discovery is its counsel's self-serving statement that they have no relevant documents. Notably, he fails to explain the steps that were taken to search for relevant documents and what searches were conducted. Further, Nautilus recently sold off some aspects of its business so the documents might be in a different business unit along with former employees who have relevant information. Also, his declaration does not speak to third-party vendors. The notion that there are no document and no witnesses that know anything about how the Nautilus products operate is ridiculous.⁵

Nor can Nautilus hide behind the fact that there was limited discovery in the First Nautilus Litigation. *Metro. Life Ins. Co. v. Bancorp Servs., L.L.C.*, 527 F.3d 1330, 1338 (Fed. Cir. 2008) (remanding a case because there was not a reasonable opportunity for plaintiff to conduct discovery in an infringement proceeding filed subsequent to a stay of a declaratory judgment proceeding in which discovery was conducted but new products were developed after the filing of the declaratory judgment action). In the First Nautilus Litigation, Nautilus produced

⁵ Nautilus' counsel's declaration suggests that there is the potential of a document spoliation issue, and Nautilus may not have taken steps to preserve evidence.

roughly 30,000 pages of discovery and no depositions were taken (Bonella Dec. at ¶3). A large portion of these documents did not relate to Nautilus' products (*id.*). There was no discovery of third-party manufacturers (*id.*). Further, similar to *Metro. Life.*, in the current litigation, some accused Nautilus products were unknown to Biosig during the First Nautilus Litigation as they were first sold after that case was filed (*id.* at ¶¶6-7). Thus, Biosig should be afforded the opportunity to conduct discovery on Nautilus' products before summary judgment is considered.

C. Nautilus' Motion for Summary Judgment of Infringement Should be Denied Because Nautilus Failed to Satisfy its Summary Judgment Burden

Nautilus argues incorrectly that there is no evidence that Nautilus' products satisfy the "means for measuring" and "means for calculating" claim limitations. But Nautilus' motion should be rejected as Nautilus failed to satisfy its summary judgment burden. As the movant for summary judgment, Nautilus bears the burden of production of pointing out that there is an absence of evidence to support Biosig's case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). In a patent case, Nautilus must show that that Biosig has "no evidence of infringement and point[] to the specific ways in which accused systems did not meet the claim limitations." *Exigent Tech. v. Atrana Solutions, Inc.*, 442 F.3d 1301, 1309 (Fed. Cir. 2006). Nautilus has utterly failed to satisfy that burden as it submitted *no evidence whatsoever* of the signal processing in Nautilus' products. Nautilus submitted no facts regarding the structure and operation of Nautilus' products in its statement of undisputed facts.

Rather than submitting evidence regarding its own products, Nautilus raises a host of irrelevant issues for the Court to consider that are hypothetical questions that the Court need not rule on as they are not ripe. For example, Nautilus asserts that there are certain algorithms in the prior art, such as certain "5-beat average" and "beat-to-beat" algorithms, that may be different than those claimed in the '753 patent's "means for measuring" and "means for calculating"

clauses. But whether the "5-beat average" or the "beat-to-beat" calculation algorithms fall within the scope of the claims is completely irrelevant because there is no evidence establishing that either algorithm is contained in any of Nautilus' products. Indeed, Nautilus does not even allege that its products have either algorithm. Thus, as there is no connection between these algorithms and Nautilus' products, Nautilus is improperly requesting an advisory and/or hypothetical judgment holding that certain algorithms do not infringe.

Nautilus also makes a hypothetical argument that the range of equivalents under 35 U.S.C. § 112, ¶6 is necessarily "narrowly limited." (D.I. 40 at 19). But Nautilus' argument is nothing but an abstract assertion for which there is no basis for this Court to rule. Here, Nautilus submitted no evidence of the processing in its products, so there is no basis to rule as to whether the actual processing in the products is the same or equivalent to that claimed. Further, equivalence under §112, ¶6 is a question of fact, opined upon by experts and determined by the ultimate finder of fact. As discussed above, there have been no fact depositions, limited document production, no discovery of third-parties, and no expert discovery. Accordingly, there is no developed record, and summary judgment is inappropriate on an abstract issue of whether the scope of equivalents is "narrow."

D. Nautilus' Motion for Summary Judgment of Noninfringement Should be Denied Because Biosig Has Submitted Sufficient Evidence to Create a Genuine Issue of Material Fact

Nautilus incorrectly contends that the summary judgment is warranted because there is insufficient evidence of infringement of the two means-plus-function clauses. But Nautilus' motion must be rejected because Biosig has submitted the declaration of Dr. Yanulis, an expert

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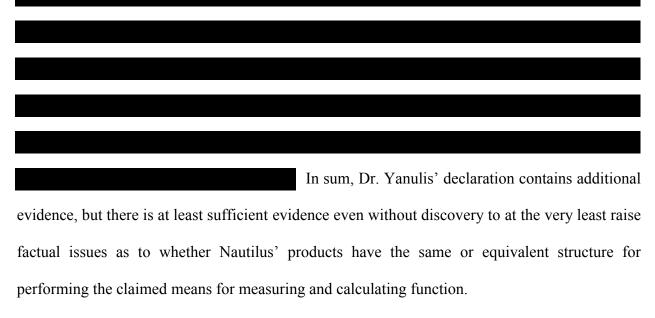
⁶ Palumbo v. Don-Joy Co., 762 F.2d 969, 975-76 (Fed. Cir. 1985) ("Whether that accused device is a § 112 equivalent . . . is a question of fact."); Cybor Corp. v. Fas Techs., 138 F.3d 1448, 1467 (Fed. Cir. 1998) ("To determine the scope of [means-plus-function] equivalents, the district court must resolve questions of fact by resorting to the expertise of the fact finder.")/

in the field. He has opined that Nautilus' products have structure for performing the claimed functions of "measuring time intervals between heart pulses on detected electrocardiograph signals" and "calculating the user's heart rate using said measured time intervals." (Yanulis Dec. at 6-12). There really should not be any dispute that Nautilus' equipment has structure for performing these exact functions because they have heart rate monitors for calculating heart rates and they need to measure time intervals between pulses to do those calculations.

Based on the limited discovery to date, Dr. Yanulis has also opined that it is more likely than not that the Nautilus products have the same or equivalent structure under 35 U.S.C. § 112, ¶6 for performing these functions. (*Id.*). As construed by the Court, the corresponding structure for the measuring function is "a microprocessor programmed according to the algorithms in Figures 4-3 and 4-7 and in column 4, lines 13-28, and equivalents under 35 U.S.C. § 112, ¶6. (D.I. 32 at 5). There is ample evidence that Nautilus' products have processors programmed with the same or similar algorithms to create a genuine issue of material fact. Nautilus' products have a microprocessor that is programmed with an algorithm for measuring the time intervals between pulses on electrocardiograph signals (Yanulis Dec. at 8-9). Nautilus

⁷ Nautilus produced a limited amount of source code in the prior litigation, but there has not been discovery regarding this source code, so the extent that Nautilus takes issue with it, Biosig is entitled to discovery.

Likewise, there is ample evidence to create at least a genuine issue of material fact
regarding the structure for performing the "means for calculating" function. The Court construed
the structure for performing this function as "a microprocessor programmed according to the
algorithms in Figs. 4-3 to 4-7 and column 4, lines 13-28, and equivalents under 35 U.S.C. §112,
¶6." (D.I. 32 at 5).



III. NAUTILUS CANNOT ESTABLISH INVALIDITY AS A MATTER OF LAW BASED ON LAWYER ASSERTION ON MATTERS CONSIDERED DURING THE REEXAMINATION PROCEEDINGS

Nautilus incorrectly asserts that the '753 patent claims are invalid for three reasons: (i) indefinite under 35 U.S.C. § 112, ¶2 for allegedly failing to differentiate prior art; (ii) indefinite under 35 U.S.C. § 112, ¶2 for supposedly being a "hybrid" claim; and (iii) invalid over the prior art for reading on the Fujisaki '200 Patent if the '753 patent claims read on Nautilus' equipment. But Nautilus cannot carry its heavy summary judgment burden of establishing invalidity as a matter of law where: (i) the Patent Office expressly stated the reasons why the '753 patent claims were patentable over the Fujisaki et al. patent; (ii) the Patent Office necessarily considered the '753 patent claims to be valid apparatus claims; (iii) Biosig has expert evidence that supports the Patent Office, and (iv) Nautilus only has inadmissible attorney assertion.

A. Factual Background: The Patent Office Rejected Nautilus' Arguments Regarding Fujisaki, et al.

During the First Nautilus Litigation, Nautilus made a strategic choice to institute a reexamination of Biosig's '753 Patent in the Patent Office and to have the Patent Office decide Nautilus' invalidity arguments. In July 2009, Nautilus instituted a second reexamination proceeding in which it made further arguments as to why Biosig's '753 Patent claims were allegedly invalid. The focus of the reexamination proceedings was Nautilus' argument that the '753 patent claims were not patentable over the Fujisaki et al reference. The Patent Office ultimately agreed with Biosig and confirmed the patentability of all without any amendments.

During the reexaminations, a point of distinction between Biosig's invention and the prior art was that that there was no disclosure of the detection and removal of EMG signals as claimed. To elaborate, the Patent Office rejected certain claims as anticipated by or obvious over U.S. Patent No. 4,444,200 (the "Fujisaki '200 Patent") (JA000344-JA000347-070 at JA000347; JA000802-815 at JA000805 & JA000165-178 at JA167). Biosig distinguished the Fujisaki '200 Patent as, *inter alia*, not teaching the "critical aspect of claim 1" namely that electromyogram signals of substantially equal magnitude and phase are detected between the electrode pairs so that the differential amplifier will subtract them to produce a substantially zero EMG signal at the output of the difference amplifier (the "EMG Whereby" clause) (JA000789-800 at JA790; *see also* JA000185-344 at 000185-186 calling the EMG Whereby Clause the "essence of this invention" and at JA000192 calling the EMG Whereby Clause the "essential and significant feature"). Biosig explained in ¶68, 69 of its response to the Patent Office that the detection and removal of the electromyogram signals are a function of the electrode size, shape, spacing, material, and circuitry (JA000201). Biosig relied on extensive testing establishing that some

⁸ Biosig cites to the '753 patent file histories previously submitted as D.I. 19, Ex. 3 that are labeled with "JA" page numbers.

electrode configurations such as that shown by Fujisaki, et al. do not remove EMG signals as claimed (JA000203; JA000328 at Pic. 23; *see also* JA000246 at ¶101, JA000330-331 at Pic. 25 & Pic. 26). As Biosig explained, the Fujisaki '200 Patent was silent regarding removing EMG signals (JA00186).

Notably, in the decision on the reexamination proceedings, the Examiner agreed with Biosig that the Fujisaki '200 Patent did not disclose electromyogram signals of substantially equal magnitude and phase that are detected between the electrode pairs so that the differential amplifier will subtract them to produce a substantially zero EMG signal at the output of the difference amplifier (JA000738-000742 at JA000742), and identified the EMG whereby clause as the claim language that the prior art did not teach (JA142).

Thus, Nautilus presented its invalidity arguments regarding Fujisaki, et al. to the patent office in two reexamination proceedings. The Patent Office addressed them and found that the '753 patent claims are patentably distinct from Fujisaki and not indefinite in light of Fujisaki. Thus, Nautilus is simply rehashing its arguments here, and its disagreement with the Patent Office is not a basis for summary judgment. (JA225-343).

B. Nautilus Did Not Satisfy its Heavy Burden of Establishing Invalidity by Clear and Convincing Evidence as a Matter of Law By Alleging Invalidity Based on Issues Considered by the Patent Office

Nautilus's invalidity arguments fail because Nautilus did not carry its summary judgment burden. Patents are presumed by law to be valid under 35 U.S.C. § 282, and therefore Nautilus bears the heavy burden of establishing invalidity by clear and convincing evidence.⁹ As the

⁹ Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2239-41 (2011) (rejecting defendant's "contention that a defendant need only persuade the jury of a patent invalidity defense by a preponderance of the evidence" and holding that invalidity must "be prove[n] by clear and convincing evidence"); Cent. Admixture Pharm. Servs., Inc. v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347, 1357-58 (Fed. Cir. 2007); Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1376 (Fed. Cir. 2009) ("infringer who raises invalidity as an affirmative defense has

movant for summary judgment, Nautilus' burden is even heavier as Nautilus is required to show that it is entitled to judgment as a matter of law and that there are no genuine issues of material fact. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986). Here, on summary judgment Nautilus' arguments must be analyzed through the "prism" of its high evidentiary burden. *Id.* at 254.

Nautilus submitted no expert evidence on the invalidity issues, instead relying on mere lawyer assertion. Nautilus' lawyers' assertions are insufficient to establish invalidity as a matter of law in light of Nautilus' heavy summary judgment burden. This is particularly true where Nautilus has the uphill battle of establishing that the Patent Office erred. Moreover, Biosig has submitted the expert declaration of Dr. George Yanulis attesting to the validity of Biosig's patent. (Yanulis Dec. at ¶13). Nautilus cannot establish invalidity as a matter of law by disagreeing with the Patent Office in the face of expert testimony when all Nautilus has for "evidence" is its lawyers' assertions.

C. Nautilus Cannot Show that the '753 Patent Claims Are Anticipated or Obvious over the Fujisaki '200 Patent as a Matter of Law Based on Lawyer Assertion When the Patent Office Explained Why the Claims are Patentable over Fujisaki and Biosig Has Submitted Expert Evidence of Validity

Nautilus incorrectly attempts to set up a dichotomy, either the patent claims are not infringed or they are invalid over Fujisaki. But Nautilus's "dichotomy" is a false one because Nautilus has failed to submit any evidence explaining the structure and operation of Nautilus' heart rate monitors. Accordingly, there is no evidence that Nautilus' heart rate monitors are using 1984 technology as taught by the dated Fujisaki reference, and no basis for Nautilus' assertion that if the claims read on Nautilus' equipment that they also read on Fujisaki. In fact, the evidence is to the contrary, as for example there is evidence that Nautilus' heart rate monitors

the ultimate burden of persuasion to prove invalidity by clear and convincing evidence, as well as the initial burden of going forward with evidence to support its invalidity allegation").

have a processor programmed to perform validity checks on the measured time intervals (Yanulis Dec. at 11-12), and there is no teaching of such a structure in Fujisaki, et al. (Yanulis Dec. at 13). Thus, Nautilus' entire argument is based on a false premise.

In any event, Biosig addresses Nautilus' invalidity arguments with respect to Fujisaki. Nautilus incorrectly asserts that the '753 patent claims are anticipated by Fujisaki under 35 U.S.C. §102. In order to show anticipation on summary judgment, Nautilus must show that as a matter of law and by clear and convincing evidence that Fujisaki discloses all of the '753 patent claim elements arranged as in the claims. *Crown Packaging Tech., Inc. v. Ball Metal Bev. Container Corp.*, 635 F.3d 1373, 1383 (Fed. Cir. 2011). If one claim limitation is missing, there is no anticipation. *Id.* Further, the issue of anticipation is a question of fact for the jury. *In re Taylor*, 2011 U.S. App. LEXIS 20421, at *4 (Fed. Cir. Oct. 6, 2011) ("Anticipation is a question of fact.") (citation and internal quotations omitted).

Nautilus has failed to carry its heavy burden as it relies on mere lawyer assertion to show invalidity, not expert testimony. *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 (Fed. Cir. 2008). This is particularly true because Nautilus has the heavy burden of showing that the Patent Office was incorrect in finding that the '753 patent claims were patentable over Fujisaki and Biosig has submitted expert testimony establishing that the '753 patent claims are valid over Fujisaki, et al. (Yanulis Dec. at 13).

Further, there is ample evidence that Fujisaki, et al. does not anticipate the '753 patent claims. As explained above, the Court construed the "means for calculating" clause as requiring

¹⁰ Netscape Communs. Corp. v. Valueclick, Inc., 684 F. Supp. 2d 699, 716-717 (E.D. Va. 2010) (holding that summary judgment on invalidity was inappropriate where the defendant did not offer expert testimony); Abraham v. Super Buy Tires, Inc., 2007 U.S. Dist. LEXIS 35403, at *15 (S.D. Cal. May 15, 2007) (denying defendant's motion for summary judgment where "Defendants offer no expert opinion on invalidity, only attorney argument").

structure in the form of a microprocessor programmed according to the algorithms in Figures 4-3 to 4-7 and in column 4, lines 13-28 and equivalents under 35 U.S.C. § 112, ¶6. (D.I. 32 at 5). As the '753 patent describes, these algorithms include validity checks, such as a validity check by comparing time measurements, and deleting a measurement if it is not within 115% or 85% of a previous measurement. (JA13 at 3:60-4:25). This is because heart rates only vary so much between beats. As Dr. Yanulis opines, Fujisaki does not disclose any validity checks on the data, much less an algorithm that is the same or equivalent to that claimed. (Yanulis Dec. at 13). Notably, Nautilus fails to point out any algorithms disclosed in Fujisaki for performing any validity checks in either its argument or in its claim chart, as Nautilus merely cites to Fujisaki's general discussion of averaging time intervals to calculate heart rates. (D.I. 40 at 25 & Ex. A at 11-12). In a slight of hand, Nautilus cites to the Charnitski '244 patent in its claim chart, but Nautilus cannot show anticipation by citing to another reference because it is black letter law that anticipation requires showing that all of the claim limitations are present in one reference, not a combination of references. Crown Packaging, 635 F.3d at 1383. In any event, Nautilus did not cite to any validity checks in Charnitski. As Biosig has submitted evidence that the "means for calculating" limitation is absent from Fujisaki, Nautilus' requests legal error with its request for a ruling as matter of law on anticipation over Fujisaki. 11

Fujisaki, et al. does not anticipate the claims for other independent reasons as it fails to disclose other claim limitations. As explained above, as the Patent Office found that Fujisaki, et al. fails to teach the "EMG whereby" clause. Nautilus does not contend otherwise. In fact,

¹¹ *In re Taylor*, 2011 U.S. App. LEXIS 20421; *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) (requiring, for a finding of anticipation, that "the prior art reference [] clearly and unequivocally disclose[s] the claimed invention or direct[s] those skilled in the art to the invention without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.").

Nautilus provided no evidence that a large portion of the claim is found in Fujisaki, et al. as it provided no evidence that any of the "whereby" clauses are found in Fujisaki, et al. *See* Nautilus Appendix A at 8-10. Thus, as Nautilus has not established a *prima facie* case of anticipation, much less one as a matter of law, and there is no reason for this Court to disagree with the Patent Office's finding that these limitations were absent from Fujisaki, et al., Nautilus' invalidity motion should be denied in its entirety.

As Nautilus cannot establish anticipation, it incorrectly argues that many of the claim limitations are functional limitations and not entitled to any patentable weight under *In re Schreiber*. But Nautilus' arguments are belied by the prosecution proceedings where Nautilus specifically alleged the functional limitations were claim limitations and that they were disclosed by Fujisaki, et al. (JA914-915). Now that the Patent Office has disagreed with Nautilus about the teachings of Fujisaki, et al., Nautilus trumps up a new argument that there is anticipation because the functional limitations are not entitled to any patentable weight.

But Nautilus is incorrect, as it misrepresents *In re Schreiber*. In that case, a patent applicant appealed from the Patent Office's findings that claims to a "dispensing top" were not patentable. 128 F.3d 1473, 1474-75 (Fed. Cir. 1997). The Federal Circuit upheld the Patent Office's rejection holding that the claims were not patentable because the product as claimed was in the prior art and a new intended use of an old product is not patentable. *Id.* at 1477. But that is irrelevant because Fujisaki, et al. lacks structural limitations including, *inter alia*, the "means for calculating" structure and the "spaced relationship" of the claimed electrodes. Unlike the situation in *In re Schreiber*, this is not a case of using a known dispensing top for passing popcorn kernals because the structure here was not shown to be known.

A full reading of *In re Schreiber* shows that it actually confirms that the '753 patent claims are valid particularly in light of the reexamination proceedings. Contrary to Nautilus' assertion that functional limitations are never entitled to any patentable weight, the Federal Circuit explained that this is not the law. *Id.* at 1478. As the Federal Circuit explained, if the patentee uses functional limitations and the "patent office has reason to believe that a functional limitation asserted to be critical for establishing novelty" may "be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristics relied on." Id. (quoting In re Swinehart, 439 F.2d 210, 213 (C.C.P.A. 1971)). In In re Schreiber, the Patent Office found that the claimed functional limitations were not entitled to patentable weight because the functional limitations were inherent in the prior art and the patent applicant had not shown otherwise. *Id.* The facts here, however, are polar opposite to those in *In re Schreiber*. Here, during the reexamination the Patent Office rejected the '753 patent claims over Fujisaki, et al., and the '753 patent applicants provided evidence including testing showing that the functional limitations, such as the EMG Whereby clause, are not inherent in Fujisaki, et al. because it has an electrode configuration that does not remove EMG signals as claimed. The Patent Office agreed citing this in its reasons for confirming the patentability. Thus, In Re Schreiber, does not hold that functional limitations are never entitled to any patentable weight, and in fact explains that the circumstances under which they are entitled to such weight directly apply here. To the extent that Nautilus disagrees with the Patent Office on what is inherent in Fujisaki, it only raises factual questions for a jury to resolve.

Almost in passing Nautilus also asserts that the '753 patent claims are invalid as obvious under 35 U.S.C. § 103 over Fujisaki, et al. and either the Charnitski et al. '244 patent or <u>The E-</u>

Factor book. Obviousness is a complicated analysis that is riddled with factual inquiries. Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 13 (1966); KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007). Again, Nautilus has failed to establish its weighty burden of establishing obviousness as a matter of law, as it addresses the obviousness issue in two sentences, provides only attorney assertion, fails to provide any expert opinion on obviousness, and provides no analysis of the four factor obviousness test. Further, the Patent Office rejected Nautilus' argument as Nautilus specifically alleged them during the reexamination proceedings (JA442-444). Moreover, Biosig has submitted Dr. Yanulis' declaration agreeing with the Patent Office and attesting to the nonobviousness. (Yanulis Dec. at 12-18). As Dr. Yanulis explains. Charnitski discloses a 3-electrode system and fails to disclose many claim limitations, and Fujisaki et al. discloses a 4 electrode system, and there is no explanation provided by Nautilus of how to combine these references and form the claimed invention. (Yanulis Dec. at 14-15). Further, The E-Factor book was distinguished during the reexamination proceedings as not having the claimed electrodes because the four electrode configuration disclosed did not have two active and two common electrodes, one for each hand (JA197). Moreover, Nautilus failed to show that The E-Factor book has the claimed "means for calculating" such as an algorithm that does a validity check. (Yanulis Dec. at 15). Thus, there are deficiencies in each of the references, no instruction on how to combine them to form the claimed invention, and insufficient evidence that the Patent Office was wrong as a matter of law. At best, Nautilus raises factual disputes.

D. Since the Court Construed the Claims of the '753 Patent, They Are Not Indefinite Under *Halliburton*

Nautilus incorrectly contends that claims 1 and 11 of the '753 Patent are invalid under *Halliburton* as indefinite under 35 U.S.C. § 112, ¶2 for failing to distinguish the "spaced relationship" claimed in the '753 Patent from the electrode configuration disclosed in the Fujisaki '200 Patent. But Nautilus' argument fails because Nautilus lacks any evidentiary support sufficient to carry its summary judgment burden, the Court necessarily found the claims definite when it construed them, the Patent Office already found the '753 patent claims sufficiently definite so as to distinguish the Fujisaki, et al. reference during two reexaminations, and Biosig has expert testimony of definiteness.

In order to establish invalidity for indefiniteness under *Halliburton*, Nautilus has the burden of showing by clear and convincing evidence that "a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history as well as her knowledge in the relevant art area." 514 F. 3d at 1249-1250. According to *Halliburton*, "[o]nly claims 'not amenable to construction' or 'insolubly ambiguous' are indefinite." *Halliburton Energy Servs. v. M-I LLC*, 514 F.3d 1244, 1250 (Fed. Cir. 2008). But Nautilus submitted no testimony from one of ordinary skill in the art, as it submitted no expert testimony. Rather, Nautilus relies on mere lawyer assertion that Nautilus' lawyers cannot determine the claim scope. Thus, Nautilus did not carry its burden. ¹²

¹² Elan Pharms., Inc. v. Mayo Found., 346 F.3d 1051, 1057 (Fed. Cir. 2003) (discussing the need for evidence on the question of whether the reference placed a person of ordinary skill in possession of the invention as claimed); Abraham, 2007 U.S. Dist. LEXIS 35403, at *15) (denying defendant's motion for summary judgment where "Defendants offer no expert opinion on invalidity, only attorney argument" and "[t]he prior art on [the claimed invention] is not so blatantly and explicitly clear that the Court can make a determination that a lay person could find anticipation by clear and convincing evidence without any expert opinion").

Nautilus' arguments also run afoul of this Court's claim construction. This Court held extensive claim constructions proceeding and found the patent claims including the term "spaced relationship" sufficiently definite such that they can be construed. As the Federal Circuit has recognized, even if claims construction is difficult, that does not render a claim invalid for indefiniteness. *Halliburton*, 514 F.3d at 1249 (citing *Exxon Research & Eng'g Co. v. U.S.*, 265 F.3d 1371, 1375 (Fed. Cir. 2001)). To avoid indefiniteness, claims must only be amenable to construction. Therefore, since the claims of the '753 Patent have been construed, it follows that they are not indefinite.

In addition, Nautilus' argument ignores the entire reexamination proceedings, which it instituted, as if they never happened. As explained above, Biosig distinguished Fujisaki, et. al as not teaching the "critical aspect of claim 1" namely that the "EMG whereby" clause of the '753 patent claims was not taught by the Fujisaki and De Val references. The test for determining the scope of the claims is readily apparent from the file history as it requires, *inter alia*, electrodes having a spaced relationship such that the EMG signals are substantially removed by certain signal processing. In fact, Biosig has submitted the declaration of Dr. Yanulis, an expert in the field, having advanced degrees in biomedical engineering and extensive experience with medical devices that process heart rate signals. (Yanulis Dec. at 1). Dr. Yanulis' has testified that he agrees with the Patent Office and the '753 patent claims are definite. (Yanulis Dec. at 12). Dr. Yanulis opined that a person of ordinary skill in the art can translate the '753 patent claims into a

¹³ Wellman, Inc. v. Eastman Chem. Co., 642 F.3d 1355, 1366 (Fed. Cir. 2011) (overturning the district court's holding that a patent specification was indefinite, stating that "[c]laims need not be plain on their face in order to avoid condemnation for indefiniteness; rather, claims must only be amenable to construction."); Haemonetics Corp. v. Baxter Healthcare Corp., 607 F.3d 776, 783 (Fed. Cir. 2010) ("[a]n accused infringer must . . . demonstrate by clear and convincing evidence that one of ordinary skill in the relevant art could not discern the boundaries of the claim based on the claim language, the specification, the prosecution history, and the knowledge in the relevant art.").

meaningful precise claim scope because one of ordinary skill in the art knows what it means to have an electrode configuration and processing that removes EMG signals. (Yanulis Dec. at 12-13). Thus, the '753 Patent claims are not insolubly ambiguous under *Halliburton*.

E. The Claims of the '753 Patent Are Not Indefinite Under *IPXL*

Using every possible legal argument it can dream up, Nautilus makes the remote argument that the '753 patent claims are indefinite for supposedly being a combined apparatus and method claim. But Nautilus confuses functional limitations with method steps in a shallow attempt to satisfy the heavy burden it bears to overcome the statutory presumption of validity. *Titan Tire*, 566 F.3d at 1376 ("infringer who raises invalidity as an affirmative defense has the ultimate burden of persuasion to prove invalidity by clear and convincing evidence"). "A 'functional limitation' is 'an attempt to define something by what it does, rather than by what it is." *Yodlee, Inc. v. Cashedge, Inc.*, 2006 U.S. Dist. LEXIS 86699, at *10-11 (N.D. Cal. Nov. 29, 2006) (quoting *Collegnet, Inc. v. Xap. Corp.*, 442 F. Supp. 2d 1036, 1062 (D. Or. 2006) (quoting Manual of Patent Examining Procedure § 2173.05(g) (8th Ed., 2001, rev. 2005))). ""[T]here is nothing inherently wrong with defining some part of an invention in functional terms. Function language does not, in and of itself, render a claim improper." *Id*.

Biosig used functional language to explain how the EMG and ECG signals are processed and in doing so had to explain that the signals are generated from a user's hands. Accordingly Biosig's claims recite a "wherein" and "whereby" clauses that explain the functional processing of signals that are generated by a person's hands, not that there has to be an actual use. This is common patent claiming as it is routine to use functional language particularly in the electrical arts to claim signal processing. Accordingly, this case is similar to the claims in *Mircoprocessor Ehancement Corp. v. Texas Insts. Inc.* in which the Federal Circuit reversed a district court's indefiniteness ruling. 520 F.3d 1367, 1373-74 (Fed. Cir. 2008). In that case, the structural

claims were for a "processor" and they recited functional processing language such as "specifying," "performing," "producing, and "enabling." *Id.* at 1371. The Federal Circuit held that the claims were not indefinite as they recited a processor capable of performing the functions, not actually performing the functions. *Id.* at 1375. Likewise, Biosig's '753 patent claims recite structure including electrodes and an amplifier and functional limitations that describe the processing that substantially removes the EMG signals.

Nautilus, however, makes a stretched attempt to shoe horn this case into a remote case finding indefiniteness for a claim that recited method steps in an apparatus claim. But Nautilus' argument fails because the claim language is significantly different in the two cases. As the Federal Circuit explained, a claim is indefinite if it recites both an apparatus and a method of using the apparatus, and in *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, the claim undisputedly required a method of use in an apparatus claim because the apparatus claim said the "user uses." 430 F.3d 1377, 1384 (Fed. Cir. 2005). In contrast, here there is no language stating that a user actually has to "use" the device. Contrary to Nautilus' assertion the claim does not state that a "user acts." Rather, the '753 patent claims recite functional language that explains how the ECG and EMG signals are processed from a user to the electrodes and through the differential amplifier.

Indeed, Nautilus' arguments are belied by Nautilus' admissions that the whereby clauses extending from column 5, line 48 to column 6, line 7 are also functional language. Tellingly, Nautilus does not contend that those functional limitations require actual "use."

Nautilus' argument regarding the prosecution history as it relates to its indefiniteness argument is erroneous. In the prosecution history, Biosig was explaining the claimed signal processing and the substantial removal of EMG signals from the ECG signals in order to explain

the invention relative to the prior art. These arguments do not import limitations into the claims much less method of use limitations into the claims.

IV. **CONCLUSION**

Nautilus' motion should be denied because it is premature. There has been no discovery in the refiled action, and there was limited discovery in the prior action. Biosig seeks discovery from Nautilus in order to meaningfully confirm that Nautilus infringes the '753 Patent. Further, Nautilus cannot establish invalidity as a matter of law based on attorney assertion. There are at the very least genuine issues of material fact that warrant denying Nautilus' motion.

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PROOF OF SERVICE

The undersigned certifies that on the 15th day of December, 2011, the foregoing pleading was electronically filed with the Court via CM-ECF. A non-redacted version will be hand filed under seal as soon as practicable. I also certify that the non-redacted version is being served via e-mail on Counsel for Defendant Nautilus, Inc.

Michael J. Bonella